

**REMARKS**

In the present amendment, claims 25, 28, 29, 32, 33, and 38 have been amended. Accordingly, claims 1-12 and 25-38 are pending in the application, with claims 1 and 25 being independent. Of the pending claims, claims 25-33, and 38 are under consideration, and claims 1-12 and 34-37 are withdrawn from consideration.

Applicants note that the claims have been amended to better comply with idiomatic English and standard U.S. practice.

Applicants also note that the specification has been amended for clarity. The amended paragraph (prior to the present amendment) recites that “it is preferable that the formation index  $y$  corresponding to a thickness of 0.3 mm of the nonwoven fabric be 50 or less **and be lower than** the value obtained using the following equation (2)

$$y = a \times \text{average fiber diameter of nonwoven fabric } (\mu\text{m}) + 55, \quad a = -4 \quad (2)”$$

(paragraph appearing at page 15, lines 2-9, emphasis added). Thus, the text indicates that the formation index,  $y$ , is lower than the value obtained with equation (2), yet the equation itself indicates that “ $y$ ” equals the value of the equation. The specification, and claims, clearly indicate throughout that  $y$  is lower than the value of equation (2), and thus, deletion of “ $y =$ ” from the aforementioned paragraph clarifies the specification, and no new matter is added with this amendment.

### **Response to Restriction Requirement**

The Office Action maintains the restriction requirement and makes the requirement final. In response, Applicants respectfully request reconsideration of the requirement and rejoinder of the non-elected claims upon allowance of the elected claims.

### **Response to Objection to the Abstract**

The Office Action objects to the Abstract due to alleged informalities. Without agreeing with or acquiescing to the objections, Applicants note that the Abstract has been amended to address the Examiner's concerns. Applicants respectfully request that the Examiner withdraw the outstanding objection to the Abstract.

### **Response to Claim Objections**

The Office Action objects to claims 28, 33, and 38 under 37 C.F.R. § 1.75(c) as allegedly failing to further limit the subject matter of previous claims.

In response, Applicants note that appropriate amendments have been made to correct these informalities. Withdrawal of the claim objections is respectfully requested.

### **Response to Rejection under 35 U.S.C. § 112, second paragraph**

The Office Action rejects claim 32 under 35 U.S.C. § 112, second paragraph, as allegedly lacking sufficient antecedent basis in base claim 25 for the limitation "a container of the filter."

In response, Applicants submit that claim 32 has been amended to recite a "a container of the flat filter," for which sufficient antecedent basis is provided in claim 25.

Withdrawal of the indefiniteness rejection of claim 32 is respectfully requested.

**Response to Rejection under 35 U.S.C. § 112, first paragraph**

The Office Action rejects claims 25-33 and 38 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description and enablement requirement.

The Office asserts that the specification does not “provide examples of leukocyte removal filter having a formation index of 50 or less corresponding to a thickness of 0.3 mm,” as claimed in the present application. The Office refers to the Examples of the specification, noting that the Examples only show filter thicknesses of 0.22; 0.23; and 0.24 mm for filters with a formation index below 50. The Office concludes that someone skilled in the art therefore would not have been convinced that Applicants were in possession of the claimed invention in its full scope and that undue experimentation would have been needed.

Applicants respectfully traverse the rejection. Applicants note that it appears the Examiner misunderstands the presently claimed invention. The meaning of the phrase “having a formation index y of 50 or less corresponding to a thickness of 0.3 mm” does not necessarily require having a filter with an actual thickness of 0.3 mm. The formation index at a corresponding value of 0.3 mm thickness has to be understood as a calibrated value, obtained by several measurements with varying filter thicknesses. Applicants refer to the teaching of the published application, paragraph [0070], which states that “the formation index is significantly affected by the thickness of the nonwoven fabric,” and describes in detail a method for proceeding if a filter material has a uniform thickness of 0.3 mm or less. In this case, “two of the three sheets of nonwoven fabric are placed upon another so that the thickness is 0.3 mm or more, and the formation index and thickness is measured. After completing the formation index measurement for all three combinations, a linear regression equation of the thickness and the formation index is created, and the formation index at a thickness of 0.3 mm is calculated using the equation.”

Applicants note that in view of the detailed description in the present specification, specifically paragraphs [0061] to [0071], a person of ordinary skill in the art would have understood that the recitation in present claim 25, i.e., “the nonwoven fabric having a formation index  $y$  of 50 or less corresponding to a thickness of 0.3 mm” refers to a calibrated value based on several actual measurements, and that it is not required to use a filter having exactly a thickness of 0.3 mm. Applicants note that calibration curves or calibration equations are a standard technical tool in all scientific fields.

Moreover, the Examiner appears to misunderstand the limitation recited, e.g., in dependent claim 27 and disclosed in the published specification in paragraph [0074], Equation (2), which requires that the formation index  $y$  must be lower than the value of:  $-4 \times \text{average fiber diameter of nonwoven fabric } (\mu\text{m}) + 55$ . The Examiner calculates for comparable Example 4 by applying Equation (2) a value of 51.4 and notes a discrepancy between the cited values in the specification of 62.6. In response, Applicants respectfully note that Equation (2) is not an equation for calculating the formation index  $y$  based on the knowledge of the average fiber diameter. Equation (2) is an empirical equation, which requires that the formation index  $y$  must be lower than the result of Equation (2). Applicants respectfully note that the specification has been amended to clarify that the value of equation (2) should not be confused with the formation index  $y$ .

In view of above remarks, Applicants believe that someone of ordinary skill in the art would have understood that Applicants were in possession of the invention, and that no undue experimentation would have been necessary to perform the presently claimed invention. Withdrawal of the written description and enablement rejections are respectfully requested.

**Response to Rejection under 35 U.S.C. § 103(a)**

The Office Action rejects claims 25-29, 33 and 38 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,048,464 to Tanaka et al., hereinafter "TANAKA."

The Office Action asserts that TANAKA teaches a leukocyte removing filter as claimed in the present application, with the only exception that TANAKA does not "teach nonwoven fabric having a thickness of 0.3 mm." The Office refers to TANAKA, Example 1, alleging that the disclosure of a "nonwoven fabric having an average diameter of 1.2  $\mu$ m, thickness of 0.2 mm and a basis weight of 40 g/m<sup>2</sup> would necessarily have formation index of less than 50."

Applicants respectfully traverse the rejection. Applicants submit that it is not possible to make conclusions about the formation index of a filter by the mere knowledge of the average fiber diameter, thickness of the filter, and its basis weight. Applicant note that the formation index is an index which indicates the uniformity of the filter material. The formation index was introduced based on the findings that uniformity all over the whole filter material is a very important parameter to achieve a higher level of filter performance compared to conventional filters. Applicants submit that Table I of the present specification also contains Comparable Examples 1-4, which are all in the range of the Example 1 of TANAKA, but do not have a formation index below 50. The Examples and Comparative Examples shown in Table 1 demonstrate that the formation index depends not only on one or two parameters, but is a much more complex interaction of different parameters, as described in the present specification, e.g., at paragraph [0068].

In this respect, Applicants also refer to Figures 4 and 5 of the present specification, which compare the concept of uniformity between conventional leukocyte removing filters (Figure 4) and the leukocyte removing filter of the present invention (Figure 5). It can be seen that the

flowability, indicated by the width of the arrows, is greatly improved by a filter using a highly uniform nonwoven fabric in accord with the present invention.

Moreover, Applicants note that in view of the photos of the filters presented in TANAKA (see TANAKA, Figures 1-3), it is clear that the distribution of the fiber material is very similar to the state shown in Figure 4 (illustrating conventional leukocyte removal filters), which makes it unnecessary to further measure/calculate a formation index.

Applicants respectfully submit that, in view of the disclosure of TANAKA, a person of ordinary skill in the art would not have been guided or motivated to make or select a filter material based on the uniformity of the material over the whole filter, and specifically a material having formation index below 50, for a corresponding thickness of 0.3 mm.

Applicants respectfully request withdrawal of the obviousness rejections of claims 25-29, 33 and 38 over TANAKA.

#### **Response to Rejection under 35 U.S.C. § 102(b)/103(a)**

The Office Action rejects claims 30-32 under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated/unpatentable over TANAKA as applied to claims 25-29, 33 and 38, in view of U.S. Patent No. 5,935,436 to Lee et al., hereinafter "LEE," and U.S. Patent No. 5,543,062 to Nishimura, hereinafter "NISHIMURA."

Applicants respectfully note that the rejections of dependent claims 30-32 are based under the assumption that independent claim 25 is unpatentable over TANAKA. Applicants submit that at least for the reasons discussed above, the presently claimed invention is not obvious over TANAKA. Claims 30-32 specify certain features of the leukocyte removal filter, i.e., the shape of

a flat or a cylindrical filter, and depend ultimately from claim 25. Accordingly, claims 30-32 are patentable for at least the same reasons that claim 25 is patentable over TANAKA. LEE and NISHIMURA do not cure the deficiencies of TANAKA.


Applicants respectfully request withdrawal of the rejections of claims 30-32 as well.

### **CONCLUSION**

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims. Applicants therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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